

Serial No.: 09/438,206

Confirmation No.: 9018

Filed: 12 November 1999

For: METHODS AND COMPOSITIONS FOR TREATING MAMMALIAN SPINAL CORD INJURIES

Remarks

The Final Office Action mailed 26 May 2004 has been received and reviewed. Claims 22 and 38 having been amended, the pending claims are claims 22-30, 38-40, 43, and 44. Support for the amendments to claims 22 and 38 is found throughout the specification, for example, at page 11, lines 15-16 and page 14, line 25. Consideration of all of the remarks set forth herein and reconsideration and withdrawal of the rejections are respectfully requested.

Examiner Interview

An interview was held at the U.S. Patent and Trademark Office on October 13, 2004 between Examiner San-ming Hui and Supervisory Patent Examiner Sreeni Padmanahban and Applicants' Representatives Nancy Johnson and Marcia Morton. At this interview, the rejections of the claims under 35 U.S.C. §112 and 35 U.S.C. §103(a) were discussed. Examiner Hui and Supervisory Patent Examiner Padmanahban are thanked for the courtesy of this interview.

Double Patenting Rejection

Claims 22-29, and 38-39 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending U.S. Patent Application No. 10/132,542. Applicants respectfully request that this rejection be held in abeyance until the identification of otherwise allowable subject matter. Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

Withdrawal of the Claim Rejections over Ducker et al.

Applicants note, with appreciation, the Examiner's withdrawal, in view of Applicants' amendments, of the rejection of claims 22, 24-29, 38, and 39 under 35 U.S.C. §102(b) as being anticipated by Ducker et al. (J. Neurosurg., 1969;30(6):693-697) and of the rejection of claims 30, 40, 43, and 44 under 35 U.S.C. §103(a) as being unpatentable over Ducker et al. in view of Potter et al. (Clin. Invest Med, 1996;19(4) Suppl. S80 #533).

Applicants respectfully submit that newly amended claims 22 and 38 (and dependent claims 23-30, 39, 40, 43, and 44) remain novel and unobvious over the teachings of Ducker et al. Claims 22-30, 38-40, 43, and 44 are drawn to methods of treating a mammalian patient having suffered an injury to its spinal cord. The method of claims 22-30 and 40 comprises "contacting the injured spinal cord . . . with a composition comprising an effective amount of at least one C1-C10 polyalkylene glycol, wherein the effective amount of at least one C1-C10 polyalkylene glycol is effective to restore nerve impulse conduction through said injured spinal cord," while the method of claims 38-40, 43, and 44 comprises "contacting the injured spinal cord . . . with a composition comprising an effective amount of polyethylene glycol, wherein the effective amount of polyethylene glycol is effective to restore nerve impulse conduction through said injured spinal cord." Thus, in the claimed methods of treating spinal cord injuries, it is the administration of at least one C1-C10 polyalkylene glycol, for example, polyethylene glycol, that is effective in restoring nerve impulse conduction through the injured spinal cord. In this regard, Applicants respectfully note that this is contrary to the Examiner's previous assertion that the instant claims encompass a method of treating spinal cord injury by employing any composition containing polyethylene glycol or C1-C10 polyalkylene glycol (Office Action, mailed 5/26/04, at page 8). Rather, the instant claims relate to methods employing compositions wherein polyethylene glycol or a C1-C10 polyalkylene glycol is an active, effective ingredient that restores nerve impulse conduction.

Applicants submit that Ducker et al. does not anticipate or make obvious the claimed methods as Ducker et al. provide no teachings of the effectiveness of at least one C1-C10 polyalkylene glycol, such as polyethylene glycol, in restoring nerve impulse conduction through the injured spinal cord. Briefly, Ducker et al. teach the use of polyethylene glycol as an inert carrier for an active ingredient, the glucocorticoid Depo-medrol® (methylpredisolone acetate). The reference teaches the administration of the glucocorticoid to the site of experimentally induced spinal cord injuries in beagles to prevent swelling and edema (Ducker et al., pages 694 and 697). Methylpredisolone acetate is practically insoluble in water (see Exhibit A with the Amendment and Response filed February 27, 2004) and polyethylene glycol is used as a

vehicle for aqueous preparations of methylpredisolone acetate (see abstract, Benzon et al., *Anesth. Analg.*, 1987;66:553-59). Thus, Applicants submit that Ducker et al. do not teach or make obvious the claimed methods, which relate to administering an effective amount at least one C1-C10 polyalkylene glycol (polyethylene glycol in claims 38-40, 43, and 44), wherein the effective amount of at least one C1-C10 polyalkylene glycol (polyethylene glycol in claims 38-40, 43, and 44) is effective to restore nerve impulse conduction through said injured spinal cord. There is simply no teaching or suggestion in Ducker or any of the cited references of the use of polyethylene glycol or a C1-C10 polyalkylene glycol as anything except as an inert carrier.

Indeed, the state of the art, prior to Applicants' invention, was such that some skilled in the art discouraged the inclusion of polyethylene glycol in compositions for treating spinal cord injuries. The Examiner is directed to Selby (*Letter to the Editor, Neurosurgery* 1983;12:591) and Benzon et al. (*Anesth. Analg.* 66:553-59, 1987), both of which demonstrate the ineffectiveness of polyethylene glycol for the treatment of spinal cord injuries. In fact, by teaching that the administration of polyethylene glycol is harmful to nervous tissues, both Selby and Benzon et al. teach away from administering polyethylene glycol for the treatment of spinal cord injuries.

Selby warns that the administration of both Depo-medrol® (methylpredisolone acetate suspensions) and its sterile vehicle, polyethylene glycol 4000 (including administration to intrathecal nerve roots), "can immediately result in the dissolution of myelin and may cause manifestations of the loss of neural function." Selby recommends that, "[b]ecause of these findings, it may be worthwhile to avoid the use of Depo-Medrol in and about nervous elements" (Selby, *Neurosurgery* 1983;12:591).

Benzon et al. note that polyethylene glycols "are heat stable and chemically inert. Their low systemic toxicity, wide range of drug capabilities, and exceptional solubilization characteristics make them useful as vehicles for drugs," including methylpredisolone acetate (page 556 of Benzon et al.). However, Benzon et al., in discussing reports of neurodysfunction associated with injections of methylpredisolone acetate, point out that "it has been postulated that the PEG vehicle is the offending agent," and teach that "[t]he occurrence of neurologic

complications after intrathecal steroid injection has been ascribed to PEG" (see abstract, page 553, and page 556 of Benzon et al.) Benzon et al. examined the neurotoxic effect of 3%, 10%, 20%, 30%, and 40% PEG solutions, looking at the depression or abolition of nerve transmission as a measure of neurotoxicity (page 556 of Benzon et al.). Benzon et al. concluded, that while 3% PEG, the concentration used clinically as an inert carrier, does not have a deleterious effect on nerve transmission (page 557, column 1, and page 558, column 2 of Benzon et al.), higher concentrations of PEG (20-30%) cause mild to moderate neurotoxicity, and exposure to a 40% PEG solution results in a complete block of nerve transmission (see page 558, column 2 of Benzon et al.).

Applicants submit that Selby and Benzon et al. provide further evidence that there was no teaching, suggestion or recognition in the art, prior to Applicants' invention, that polyethylene glycol or C1-C10 polyalkylene glycols are effective in restoring nerve impulse conduction through an injured spinal cord.

The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 22-30, 38-40 and 43-44 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserted that the originally filed specification and claims do not provide support for the recitation "wherein the composition does not contain benzyl alcohol" in claims 22 and 38. Applicants respectfully submit that this rejection is moot in view of the amendment of claims 22 and 38, deleting the recitation "wherein the composition does not contain benzyl alcohol."

The 35 U.S.C. §103(a) Rejection

The Examiner rejected claims 22, 24-30, 38-40 and 43-44 under 35 U.S.C. §103(a) as being unpatentable over Balasubramanian (U.S. Patent No. 5,382,584) in view of Potter et al. (Clin. Invest Med, 1996;19(4) Suppl. S80 #533). This rejection is respectfully traversed.

Applicants respectfully submit that the Examiner has not met the burden of establishing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three criteria must be met. First, the prior art reference (or references) must teach or suggest all of the claim limitations. Second, there must be some suggestion or motivation, either in the cited reference (or references), or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Third, there must be a reasonable expectation of success. M.P.E.P. § 2142 (citing *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991)).

Claim 22 (and dependent claims 23-30 and 44) is drawn to a method of treating a mammalian patient having suffered an injury to its spinal cord with a composition comprising an effective amount of at least one C₁-C₁₀ polyalkylene glycol, wherein the effective amount of at least one C₁-C₁₀ polyalkylene glycol is effective to restore nerve impulse conduction through said injured spinal cord. Claim 38 (and dependent claims 39, 40, 43 and 44) is drawn to a method of treating a mammalian patient having suffered an injury to its spinal cord with a composition comprising an effective amount of polyethylene glycol, wherein the effective amount of polyethylene glycol is effective to restore nerve impulse conduction through said injured spinal cord.

Balasubramanian teaches that a series of compounds that are 1-piperazinyl-N-phenylacetamide derivatives of 4,5-diphenyl-oxazoles, thiazoles, and imidazoles were found to provide effective antiischemic protection for central nervous system and cardiac tissue, particularly neurons (Abstract). The compounds were described as novel adenosine reuptake inhibitors (column 1, lines 19-22). The only teachings in Balasubramanian making reference to the use of polyethylene glycol are found in the paragraph bridging columns five and six, which states that polyethylene glycol may be used as 1) a lubricant when administering the active ingredient in tablet or capsule form (column 6, lines 4-11); and 2) a vehicle for the parenteral administration of an active compound (column 6, lines 12-23).

Potter discusses 4-aminopyridine as a K⁺ channel blocking agent that enhances nerve conduction through areas of demyelination in patients with spinal cord injuries.

Applicants submit that Balasubramanian in view of Potter does not teach or suggest all of the limitations of the claimed methods of treating spinal cord injuries. The methods of claims 22-20, 38-40, 43, and 44 are methods of treating spinal cord injuries by contacting the injured spinal cord with *an effective amount* of "at least one C₁-C₁₀ polyalkylene glycol" (claims 22-30 and 44) or "polyethylene glycol" (claims 38-40, 43 and 44), *wherein the effective amount* of the at least one C₁-C₁₀ polyalkylene glycol or the polyethylene glycol *is effective to restore nerve impulse conduction through said injured spinal cord*. Balasubramanian teaches polyethylene glycols for use as non-toxic, inert, and pharmaceutically acceptable carriers (column 5, lines 20-23) in the preparation of pharmaceutical compositions of adenosine reuptake inhibitors. Balasubramanian does not teach or suggest that the administration of polyethylene glycol is effective to treat spinal cord injuries and, thus, does not teach the administration of *an effective amount* of polyethylene glycol, *wherein the effective amount* of polyethylene glycol *is effective to restore nerve impulse conduction through said injured spinal cord*. Balasubramanian does not teach or suggest all the limitations of the claimed methods. This deficiency is not corrected by Potter, which is silent as to the use of polyethylene glycol or C₁-C₁₀ polyalkylene glycols. Balasubramanian in view of Potter does not teach or suggest all of the limitations of the claimed methods of treating spinal cord injuries.

Applicants further submit that the Examiner has failed to establish the existence of a motivation to combine the cited references. Indeed, there is no suggestion or motivation to combine the disclosure of Balasubramanian with that of Potter. Balasubramanian is directed to the administration of compounds that are adenosine reuptake inhibitors to provide effective antiischemic protection for the central nervous system and cardiac tissue. The limited teachings found in Balasubramanian pertaining to polyethylene glycol are very clearly directed to the use of polyethylene glycols as non-toxic, inert, pharmaceutically acceptable carriers (see col. 5, lines 15-23 and col. 6, lines 10-11 and lines 22-23). Potter, on the other hand, describes the administration of 4-aminopyridine as a K⁺ channel blocking agent, for the treatment of nerve conduction defects due to demyelination.

Citing *In re Kerkhoven*, the Examiner asserted that the motivation to combine is found in the teachings of both Balasubramanian and Potter, "that both agents are known to be useful in treating spinal cord injuries. Therefore, absent evidence to the contrary, employing them concomitantly for treating the very same condition, spinal cord injuries, would be obvious" and an additive effect would be reasonably expected (page 8, Office Action mailed May 26, 2004). Applicants strongly disagree and respectfully submit that the Examiner is misapplying the holding of *In re Kerkhoven*. With *In re Kerkhoven*, the court held that "[i]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be *useful for the same purpose*, in order to form a third composition which is to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art" (*In re Kerkhoven* 626 F.2d 846, 850 (US Court of Customs and Patent Appeals, 1980) (a copy of which is provided as Appendix A) (emphasis added). First, Applicants submit that the holding of *In re Kerkhoven* pertains to compositions and is not relevant to the claimed methods of treatment. Further, Applicants submit that Balasubramanian and Potter do not each teach compositions which are *useful for the same purpose*. Rather, Balasubramanian teaches compositions including polyethylene glycol as an inert carrier. Potter teaches compositions of 4-aminopyridine for the treatment of nerve demyelination. These are distinctly different purposes. One of ordinary skill in the art would not be motivated to combine the teachings of Balasubramanian with the teachings of Potter to obtain the methods of claims 22-30, 38-40, 43, and 44.

Applicants further submit that the Examiner has failed to establish the existence of a reasonable expectation of success in combining the disclosure of Balasubramanian with that of Potter. In short, Balasubramanian, considered alone or in combination with Potter, fails to teach that polyethylene glycol or a C1-C10 polyalkylene glycol is effective to treat spinal cord injuries. Moreover, the teachings of Selby and Benzon et al., previously discussed above, express concerns over the harmful effects of administering polyethylene glycol to nervous tissue, thereby teaching away from combining the teachings of Balasubramanian and Potter, and away from the claimed invention.

In addition, Applicants emphasize that the Examiner should recognize and consider the unexpected results achieved in the claimed methods. In this regard, Applicants direct the Examiner's attention to page 13, line 26 to page 14, line 2 of the specification, which clearly teaches that "it has unexpectedly been observed that treatment of the injured mammalian spinal cord with a potassium channel blocker, such as 4-aminopyridine, after treatment with a fusion agent, such as polyethylene glycol, can result in synergistic repair of the spinal cord. For example, CAPs increase in conduction when both agents are used by a percentage greater than the sum of the percent increase in conduction of the CAPs when injured spinal cords are treated alone with either the fusion agent or the potassium channel blocker." Thus, treatment with both a fusion agent and a potassium channel blocker is not merely additive and claims 30, 40, and 43 cannot be obvious over the combined teachings of Balasubramanian and Potter.

Applicants therefore submit that the Examiner has not met the burden of establishing a *prima facie* case for the aforementioned reasons, and moreover, has not established that the invention, as claimed, is rendered obvious. Accordingly, withdrawal of this rejection of the claims under 35 U.S.C. § 103 is respectfully requested.

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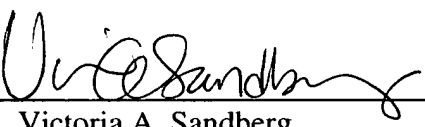
Summary

It is respectfully submitted that the pending claims 22-30, 38-40, 43, and 44 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
SHI et al.

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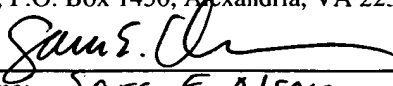
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APPENDIX A

In re Kerkhoven

(CCPA)

205 USPQ 1069

Decided May 15, 1980

No. 79-586

U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Patentability -- Composition of matter (§ 51.30)

Patentability -- Invention -- Specific cases -- Chemical (§ 51.5093)

It is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, claims that require no more than mixing together of two conventional spray-dried detergents set forth prima facie obvious subject matter.

2. Patentability -- Composition of matter (§ 51.30)

Patentability -- Evidence of -- Comparison with allowed claims or patents (§ 51.457)

Comparative test data that is not commensurate with claims' scope offered as evidence of superiority of claimed method does not rebut prima facie case of obviousness.

3. Patentability -- Composition of matter (§ 51.30)

Patentability -- Invention -- In general (§ 51.501)

Patentability -- Invention -- Specific cases -- Chemical (§ 51.5093)

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Patentability -- New use or function -- Nonanalogous art (§ 51.557)

Problem of how to introduce more than one color into detergent and problem of how to improve flow characteristics of mixed-active detergent are quite remote; mere knowledge that simultaneous spray-drying multiple slurries was useful technique in production of multi-colored detergents would not have suggested anything about effect of simultaneous spray-drying slurries having different active detergent contents, one being primarily if not exclusively anionic in nature and other being primarily if not exclusively nonionic in nature, on flow characteristics of final mixed-active product; claimed process, considered as a whole, as required by 35 U.S.C. 103, would not have been prima facie obvious to one skilled in art at time invention was made where one skilled in art working at that time on problem invention solved would not have been motivated or guided by prior art to arrive at claimed process.

Particular patents -- Detergent

Kerkhoven, Production of Detergent Compositions, rejection of claims 2-4, 9, and 14 affirmed; rejection of claim 5 reversed.

Case History and Disposition:

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**Appeal from Patent and Trademark Office Board of Appeals.
Application for patent of Frederik Johan Kerkhoven, Serial No.
501,956, filed Aug. 30, 1974. From decision rejecting claims 2-5,**

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**9, and 14, applicant appeals. Modified; Miller, Judge, with whom
Markey, Chief Judge, joins, dissenting in part with opinion.
Attorneys:**

James J. Farrell, Edgewater, N.J., for appellant.

**Joseph F. Nakamura (Gerald H. Bjorge, of counsel) for
Commissioner of Patents and Trademarks.**

Judge:

Before Markey, Chief Judge, Rich, Baldwin, and Miller, Associate Judges, and Newman, * Judge.

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Opinion Text

Opinion By:

Newman, Judge.

This is an appeal from the decision of the United States Patent and Trademark Office (PTO) Board of Appeals (board) sustaining the examiner's rejection under 35 USC 103 of claims 2-5, 9 and 14 of application serial No. 501,956, filed August 30, 1974, for "Production of Detergent Compositions." We modify.

Background

The Invention

Appellant claims a process for the production of particulate detergent compositions containing a mixture of anionic ¹ and nonionic ² active detergent materials. Appellant explains in his specification that the detergent-making art often prefers such detergents to achieve optimal detergent properties, and he notes that the most commonly used active detergent combination is a mixture of anionic fatty acid soaps, anionic synthetic non-soap detergents, and nonionic detergents. Detergents made from this combination of ingredients are called mixed-active detergents.

Appellant's invention is generic in the sense that it covers two separate and distinct methods of producing mixed-active particulate detergents, each method including the common step of forming at least two slurries ³ of detergent ingredients, the active detergent content of one slurry being primarily if not exclusively anionic in nature and the active detergent content of the other slurry being primarily if not exclusively nonionic in nature. Under one of these methods, the slurries are independently dried and the resulting products are mixed. Under the other method, the slurries are simultaneously dried and mixed.

Appealed claims 2-4, 9 and 14 are drafted broadly enough to cover both of these modes of operation. Claim 14 is illustrative:

14. A process for preparing a spray-dried detergent composition comprising by weight 5-80% of builders, 0-50% fillers and 5-60% of active detergent materials consisting essentially of a mixture of 20-80% by weight of anionic detergents of which 10-90% by weight is a fatty acid soap, and 80-20% by weight of nonionic detergents, which process comprises forming approximately equal proportions of at least two aqueous slurries A and B, slurry A being composed of a builder slurry incorporating therein an active detergent component consisting essentially of 60-100% by weight of anionic detergents and 0-40% by weight of nonionic detergents, slurry B being composed of a builder slurry incorporating therein an active detergent component consisting essentially of 0-40% by weight of anionic detergents and 60-100% by weight of nonionic detergents, treating said slurries as separate streams in at least on spray-drying equipment and collecting/mixing the dried products to form a homogeneous mixture of particulate material comprising said detergent composition.

Appealed claim 5, however, is limited to only the simultaneously dry and mix method. Claim 5 reads as follows:

5. A process according to claim 14, in which slurries A and B are spray-

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dried simultaneously in one spray-drying tower through separate nozzle systems, having points of entry on the tower at substantially equal height level of the tower.

According to appellant, the conventional manner of making mixed-active particulate detergents had been to mix all of the ingredients together in one slurry and then spray-dry the slurry. Appellant alleges that this single-slurry technique produces detergents having poor flow characteristics, whereas his multi-slurry methods produce detergents having excellent flow characteristics.

To prove this, appellant conducted tests comparing the flow characteristics of detergents made by these processes. The results from these tests show that mixed-ac

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tive detergents made according to both of the claimed multi-slurry methods had good flow characteristics. On the other hand, detergents comprising the same ingredients made by the above-described single-slurry process had poor flow characteristics. The tests, however, did not compare the flow characteristics of compositions containing partially prehydrated sodium tripolyphosphate builder.

The Prior Art

The PTO has cited the following references as prior art:

Coffey ⁴ describes a process for the production of mixed-active particulate detergents having good flow characteristics. Coffey uses a single slurry technique, i.e., all the ingredients are mixed together in one slurry which is then spray-dried. According to Coffey, his detergents have good flow characteristics because he includes in the slurry partially prehydrated sodium tripolyphosphate builder.

Cavataio ⁵ and Tofflemire ⁶ disclose processes for the production of multicolor particulate detergents. The multi-color effect is achieved by simultaneously spray-drying a natural colored detergent slurry and a colored detergent slurry through separate nozzles in the same spray-drying tower. In Tofflemire, the nozzles are at the same height in the tower.

Colgate ⁷ teaches mixed-active detergents having enhanced soil-suspending properties. The flow characteristics of these detergents are not discussed.

Ruff ⁸ discloses anionic spray-dried detergents and nonionic spray-dried detergents having tarnish inhibiting properties.

Examiner's Rejection

The examiner rejected all of the appealed claims under 35 USC 103 as unpatentable either over Cavataio in view of Colgate, Coffey, Ruff and Tofflemire, or over Colgate and Coffey in view of Cavataio, Ruff and Tofflemire. He explained that the claims require no more than the mixing of two conventional spray-dried detergent compositions, and concluded that the mere mixing of two compositions each taught for the same purpose, in the absence of a showing of unexpected results, is obvious. In support of this proposition, the examiner cited *In re Crockett*, 47 CCPA 1018, 279 F.2d 274, 126 USPQ 186 (1960).

The examiner determined that appellant had not demonstrated any unexpected

advantage for the claimed process. He pointed out that although the claims encompass the use of prehydrated sodium tripolyphosphate builder, appellant had not shown that the product produced from his process was superior to that obtained from Coffey's process, when prehydrated sodium tripolyphosphate was used. The examiner also noted that appellant had not demonstrated that Colgate's product had poor flow characteristics.

In his original rejection, the examiner did not comment on the independent patentability of claim 5. However, in the examiner's Answer to appellant's brief before the board, the examiner acknowledged that claim 5 presented the additional issue of whether it would be obvious to spray dry the two compositions simultaneously in one tower through separate nozzles at an equal height level. The examiner concluded that this would have been obvious, reasoning:

Appellant has neither argued nor demonstrated that this method of simultaneous spray drying in a single tower provides any unexpected results. Further, this process would be suggested by the teachings in Tofflemire and appellant's admission in the sentence bridging pages 27 and 28 of his brief that "given the long standing practice of spray drying with a multiplicity of nozzles, the *possibility* of introducing separate streams to any or all of these separate nozzles would be obvious to anyone of ordinary skill in the art". [Emphasis in original.]

Appellant responded to this point in his reply brief before the board with the following:

The Examiner's arguments with respect to claim five, that applicant has

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admitted the possibility of introducing separate streams to any or all of separate nozzles as being obvious, does not relate to whether one skilled in the art would actually do such a thing without applicant's teaching. Indeed to argue the impossibility of introducing separate slurries to separate nozzles and spray drying them simultaneously would be fruitless.

Tofflemire is directed to producing a multicolored particulate detergent and has nothing to do with combining two slurries such as applicant has claimed.

Board's Rejection

The board affirmed the examiner's rejection adding that in its opinion one skilled in this art, knowing that individual detergents or certain mixtures of detergents produce particles having good free-flow characteristics, would understand that the detergents desired in the final composition may be dried separately and then mixed. The board did not address the issue of the independent patentability of claim 5.

Appellant's Argument

Appellant contends that there is no suggestion in the prior art to split the active detergents into two specific slurries and spray-dry them either simultaneously to obtain a final product or separately and then mix them to obtain a final product. Therefore, appellant argues, no prima facie case of obviousness exists, and a showing of unexpected results is not required.

Appellant maintains that, as was the case in *In re Sponnoble*, 56 CCPA 823, 405 F.2d 578, 160 USPQ 237 (1969), appellant's invention here is the discovery of the source of a

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problem and the finding of a solution for that problem. Appellant points out that none of the cited references except Coffey recognized the problem here, and that Coffey employed a different route to solve it.

Appellant notes that claim 5 which calls for simultaneous spray-drying is even more remote from the examiner's references than the other appealed claims. Appellant submits that the process of claim 5 would not be performed by the mere mixing of two known spray-dried detergents.

Solicitor's Argument

The solicitor asserts that one of ordinary skill in the art -- faced with the problem of poorly flowing mixed-active detergents prepared by spray-drying one slurry containing all detergents, and armed with the knowledge that detergent compositions do not present such difficulties if the active detergent component is not a mixture of different active detergents -- would readily understand that the detergents desired in the final composition may be dried separately and then mixed. He submits that the problem and its source were known, and that the solution thereto claimed herein would have been obvious.

In his brief, the solicitor does not address the issue of the independent patentability of claim 5. When asked to comment on the rejection of claim 5 at oral argument, the solicitor stated that the basis for the PTO's case of obviousness for claim 5 was: (1) appellant's description of the prior art before the board, wherein appellant stated that Cavataio makes detergent compositions by spray drying two detergent slurries of different chemical composition simultaneously in a tower; (2) the disclosure in Tofflemire that shows the feature of simultaneous spray-drying two slurries from the same height in a spray-drying tower; and (3) appellant's admission that simultaneous spray-drying of two detergent slurries was known.

Opinion

[1] It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art. In the case at bar, appealed claims 2-4, 9 and 14 require no more than the mixing together of two conventional spray-dried detergents. Thus, these claims set forth prima facie obvious subject matter.

[2] The comparative test data offered by appellant as evidence of the superiority of this claimed method does not rebut the prima facie case of obviousness because it is not commensurate in scope with the claims. The claims are broad enough to cover multi-slurry-produced detergent compositions containing partially pre-hydrated sodium tripolyphosphate builder. Coffey teaches that single-slurry-produced detergent compositions containing this builder have good flow characteristics. Appellant's attorney admits that appellant has not run any tests comparing his multi-slurry-produced

detergent compositions containing this builder. Thus, appellant has failed to prove the superiority of his multi-slurry technique over the prior art's single-slurry technique for the production of detergent compositions containing this builder. Having failed to do this, appellant has not proven the superiority of the multi-slurry technique over the single-slurry technique for all compositions covered by the claims.

Claim 5

In review of this application, the board lumped claim 5 together with the rest of appellant's claims. Appellant specifically objects to this treatment -- and we agree.

Claim 5 sets forth an alternative process for making a mixed-active spray-dried particulate detergent. Whereas the other claims on appeal include in their coverage the process of merely combining a known anionic spray-dried particulate detergent with a known nonionic spray-dried particulate detergent to form a mixed-active particulate detergent product, claim 5 is limited to the process of making a mixed-active particulate detergent product by simultaneously spray-drying through separate nozzle systems in one spray-drying tower one detergent slurry, having an active detergent content of 60-100% anionic and 0-40% nonionic, and another detergent slurry having an active detergent content of 60-100% nonionic and 0-40% anionic.

Searching the references, we find no support for the PTO's prima facie case of obviousness for claim 5. Coffey, the only reference which describes a prior art method for obtaining good-flowing mixed-active particulate detergents, does not use simultaneous spray-drying, but rather teaches a single-slurry technique that requires partially pre-hydrated sodium tripolyphosphate builder.

Coffey explains that it was an object of his invention "to enable the production of satisfactory detergent compositions comprising appreciable proportions of [nonionic active detergent ingredients]." According to Coffey, "it [had] not been readily possible, [prior to Coffey's invention], to make acceptable detergent compositions in powdered or granular form incorporating appreciable quantities of [nonionic active detergent ingredients], * * *, as such compositions [were] sticky and [had] poor flow properties rendering their production and packaging difficult and so making them unsatisfactory for commercial use." Coffey discloses, however, that under his invention: "Such compositions may be made with good flow properties and texture which are retained during storage, * * *." The "essential feature" of Coffey's method for making satisfactory mixed-active detergent compositions is the use of partially pre-hydrated sodium tripolyphosphate builder.

Unlike Coffey's method, appellant's process (claim 5) for making a mixed active detergent with good flow characteristics does not rely on partially pre-hydrated sodium tripolyphosphate builder. Rather, appellant solves this flow problem by utilizing the technique of simultaneously spray-drying through separate nozzle systems in one spray-drying tower one detergent slurry having an active detergent content that is primarily if not exclusively anionic and another detergent slurry having an active detergent content that is primarily if not exclusively nonionic. Although simultaneous spray-drying of multiple slurries did not originate with appellant, on this record he appears to have been the first to utilize this technique with slurries having different active detergent contents, one being primarily if not exclusively anionic in nature and the other being primarily if not exclusively nonionic in nature, in order to improve the flow characteristics of the

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final mixed-active product.

[3] In the past, simultaneous spray-drying of multiple slurries was limited to the production of multicolor detergents wherein the specific active detergent content of the slurries was beside the point.⁹ We conclude that the problem of how to introduce more than one color into a detergent and the problem of how to improve the flow characteristics of a mixed-active detergent are quite remote. Mere knowledge that simultaneous spray-drying multiple slurries was a useful technique in the production of multi-colored detergents would not have suggested anything about the effect of simultaneous spray-drying slurries having different active detergent contents, one being primarily if not exclusively anionic in

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nature and the other being primarily if not exclusively nonionic in nature, on the flow characteristics of the final mixed-active product. Consequently, one skilled in this art, working at the time appellant's invention was made on the problem of how to obtain good flow characteristics in mixed-active spray-dried detergents without resort to partially pre-hydrated sodium tripolyphosphate builder, would not have been motivated or guided by the prior art to arrive at the process appellant is claiming in claim 5, that is, a process for making a mixed-active detergent wherein the flow characteristic problem is solved by resort to the simultaneous spray-drying technique heretofore only used in the production of multi-colored detergents. For this reason, we hold that the process described in claim 5, considered *as a whole* as required by 35 USC 103, would not have been *prima facie* obvious to one skilled in the art at the time this invention was made. Cf. *In re Sponnoble*, 56 CCPA 823, 405 F.2d 578, 160 USPQ 237 (1969); *In re Kuehl*, 475 F.2d 658, 177 USPQ 250 (CCPA 1973).

Accordingly, the decision of the board is *affirmed* with regard to claims 2-4, 9 and 14, and *reversed* as to claim 5.

Modified.

Footnotes

Footnote 1. An anionic substance is one which is negatively charged.

Footnote 2. A nonionic substance is one which is electrically neutral, that is, it does not have either a positive or negative charge.

Footnote 3. A slurry is a watery mixture or suspension of insoluble matter.

Footnote 4. Canadian patent to Coffey, Griffiths, and Naylor, No. 852173, issued September 22, 1970, for "Process for the Production of Detergent Compositions."

Footnote 5. U.S. patent to Cavataio and Monick, No. 3,519,054, issued July 7, 1970, for "Process for Producing a Particulate Product."

Footnote 6. U.S. patent to Tofflemire, No. 3,357,476, issued December 12, 1967, for "Process and Apparatus for Spray Drying Multi-Colored Detergent Particles."

Footnote 7. British patent specification of Colgate-Palmolive Company, No. 931,438, published July 17, 1963, for "Solid Detergent Composition."

Footnote 8. U.S. patent to Ruff, No. 2,861,954, issued November 25, 1958, for

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"Polyphosphate Compositions Containing Soap and 2-Mercaptothiazoline."

Footnote 9. Although Cavataio implies that the colored slurry could be different from the matrix slurry composition-wise, nowhere does he teach or even hint at the particular difference here claimed, i.e., that the slurries have different active detergent contents, one being primarily if not exclusively anionic in nature and the other being primarily if not exclusively nonionic in nature. In point of fact, Cavataio's only illustration of this point is an example wherein one slurry contains none of the active detergent material.

Dissenting Opinion Text

Dissent By:

Miller, Judge, with whom Markey, Chief Judge, joins, dissenting in part.

I cannot agree that the rejection of claim 5, which requires simultaneous spray-drying and mixing of two conventional detergent slurries, should be reversed. The majority opinion recognizes that the motivation for one of ordinary skill in the art to mix the dried detergents together after independent spray-drying follows logically from the prior art. In *re Susi* and *In re Crockett*, both cited in the majority opinion. Nevertheless, it concludes that mixing them during *simultaneous* spray-drying would have been beyond the level of ordinary skill in the detergent-making art, even though, as the majority opinion recognizes, simultaneous spray-drying of multiple slurries is a conventional process in that art.¹

How or why such mixing would have been beyond the level of ordinary skill in the art is not explained except by the statement that there would have been no motivation therefor, because the prior art simultaneous spray-drying technique had only been used in the production of multicolored detergents. However, this position is untenable, because Cavataio et al. teach that two detergent slurries to be simultaneously spray-dried can be of *different compositions* as well as of different colors.² Thus, motivation to use *any* two conventional slurries (having different active detergent contents) in the Cavataio et al. process would have been provided one of ordinary skill in the art, and a prima facie case of obviousness is established.

The majority opinion's reversal of the rejection of claim 5 clearly relies upon its conclusion that appellant "solves this flow problem" (the "sticky and poor flow properties" of detergent compositions related by Coffey), accepting as fact that appellant's process produces detergents "with good flow characteristics." However, in affirming the rejection of all the other claims, the majority opinion does not accept appellant's "good flow characteristics" test data as sufficient to rebut a prima facie case of obviousness. Moreover, it does not necessarily follow that a product possessing nonobvious properties renders a process for making that product nonobvious. As Judge Rich explained in his concurring opinion in *In re Larsen*, 49 CCPA 711, 716-17, 292 F.2d 531, 534-36, 130 USPQ 209, 212-13 (1961):

[I]f it be the fact that the final compound AB possesses unique, unexpected, surprising, or highly useful properties, they *inhere in the product* AB, not in A alone, B alone, *or in the process* of reacting them. While such attributes in a

product may make it, the product, patentable they do not make the process patentable because they are in no way a part of the process. * * *

There is a certain amount of logic in holding a product to be unobvious

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because of the discovery in it of unobvious properties * * *. But I see neither logic nor sound interpretation of the patent law in transferring such properties from the product in which they inhere to a process of making the product in which they do not.

See *In re Hoeksema*, 51 CCPA 1474, 1478, 332 F.2d 374, 377, 141 USPQ 733, 735-36 (1964), pointing out:

In *In re Larsen* * * * this court held a process to be obvious although it produced a product which, because of its unexpected properties, was unobvious.

See *In re Kuehl*, 475 F.2d 658, 665, 177 USPQ 250, 255-56 (1973), in which the unanimous opinion by Judge Roth points out that "each statutory class of claims must be considered independently on its own merits" and that "an applicant does not get such [process] claims just because the product is new and unobvious." Appellant's citation of *In re Sponnoble*, 56 CCPA 823, 405 F.2d 578, 160 USPQ 237 (1969), is not apt, because the appealed claim with a limitation directed to the solution of a problem.

Although the manufacture of detergents may involve chemical reactions in process steps, claim 5 involves merely the physical process of simultaneously spray-drying two known slurries, and there is no indication that a chemical reaction occurs in the spray-drying tower. Accordingly, the uncertainty and unpredictability often associated with the chemical arts is not present here.

With respect to appellant's claim limitation that the nozzles be located at a "substantially equal height level of the tower," Cavataio et al. disclose that the point of entry of the second liquid can be as close as 15% "below the level of the point of entry of the first liquid, the percentage based on the distance from the bottom of the spray tower to the point of entry of the first liquid." Moreover, the Tofflemire reference (U.S. Patent 3,357,476) expressly discloses the simultaneous spray drying of two different detergents (one colored, the other not colored) at the same height.

I would hold that the Patent and Trademark Office has established a prima facie case of obviousness of claim 5 and that this has not been rebutted by appellant's comparative test data, the same not being commensurate in scope with the claim, as clearly pointed out in the majority opinion.

Footnotes

Footnote 1. The majority opinion says that appellant appears to have been the first to utilize simultaneous spray-drying with slurries having different active detergent contents, but, at oral argument, counsel for appellant stated that it made no difference whether the compositions were separately dried before mixing or simultaneously dried and mixed.

Footnote 2. Cavataio et al. state that "both the matrix and the contrasting colored liquid are in the form of slurries which contain the necessary components for a complete

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detergent composition." The majority opinion offers no reason for limiting this teaching of Cavataio et al. to the specific slurry compositions used in their several examples.

Footnote * The Honorable Bernard Newman, United States Customs Court, sitting by designation.

- End of Case -

